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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/198,018	11/23/98	ASTLE	T 130-125

021091
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EXAMINER	
BEX, P	
ART UNIT	PAPER NUMBER
1743	8

DATE MAILED: 06/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/198,018	Applicant(s) ASTLE, THOMAS W.	
	Examiner P. K. Bex	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *06 April 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *19,20 and 24-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 21-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1, now recites a plurality of *thermoformed* chemical receiving wells. However, there is no support which has been cited by Applicant or found by the Examiner which supports the use of *thermoformed* chemical receiving wells. No manufacturing method for "thermally forming" or "thermoforming" the wells is disclosed in the specification or the claims. Additionally, the claims are drawn to method of chemical compound storage *not* the formation of the wells.

Claim 3, recites a roll having dimensions about four inches wide by sixteen inches *long*. The specification supports a roll having dimensions about four inches wide by sixteen inches in *diameter*, see page 11, line 10.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1,15 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 3, the use of the word "thermoformed" creates confusion and uncertainty as to what is actually meant by "thermoformed chemical receiving wells". The process of thermoforming is clearly defined and accepted within the art to mean a process to give a final shape to a thermoplastic with the aid of heat and usually pressure.

Claim 15, para b, it is not clear as to how the holes between the chemical receiving wells function to evacuate the space between the wells. The specification discloses the application of a vacuum 80 to evacuate any entrapped air, see page 16, line 8-10. No such vacuum means is disclosed in the claims. Further, is it not clear as to how the evacuation is applied, i.e. through the holes?

Claim 30, line 2, recites the limitation "indexing repetitive patterns". There is insufficient antecedent basis for this limitation in the claim. Further, it is not clear as to what applicant means by "repetitive patterns".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 21-23 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Guigan (USP 3,620,678).

Guigan anticipates the instant claims by teaching a method of chemical compound storage comprising providing a longitudinally extending carrier tape 1,12 having a plurality of thermoformed chemical receiving wells 3, 13, 168 and adding to each of the chemical receiving wells a chemical compound. Note: Guigan clearly teaches the use a thermoplastic material (column 4, line 34) and heat and pressure to form the wells (column 9, lines 23-30, Fig 1-3, and 9).

The liquid tight sealing material 10 placed over the chemical receiving wells is taught at (column 3, lines 18-43, Fig. 3 and Fig. 18).

The sealing material being heat sealed to the carrier tape is taught at col. 4, lines 30-38.

The tractor drive 150 for indexing repetitive patterns of wells is taught at Fig. 20.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 4-8 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guigan (USP 3,620,678) in view of Anderson (USP 5,092,466).

Guigan as discussed previously, does not disclose repetitive matrixes with a unique identifier. However, such an identifier is considered conventional in the art, see Anderson. Anderson does teach repetitive matrix with a unique identifier 22, 24 (Fig. 1). Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the chemical storage apparatus of Guigan with the identification means of Anderson, in order to reduce the costs of storage, inventory management, and distribution of a very large number of biological samples (col. 2, lines 17-23).

The sealing material heat sealed to the carrier tape is taught by Guigan at col. 4, lines 30-62.

Regarding the specific material of the carrier tape, it would have been obvious to one of ordinary skill in the art to have made the carrier tape of Guigan with the polycarbonate, polystyrene or polypropylene, in order to ensure that the carrier tape is chemically inert with respect to the substances being stored. Since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

With respect to the number of chemical receiving wells in repetitive matrixes selected from the group consisting of 8 by 12 with a spacing of 9 mm between centers, etc. It would have

been an obvious matter of design choice to have made the chemical receiving wells in repetitive matrixes selected from the group consisting of 8 by 12 with a spacing of 9 mm between centers of Anderson in order to increase amount of samples which are assayed. Further, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

10. Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guigan (USP 3,620,678) in view of Hansen et al. (USP 4,565,783).

Guigan does not teach the sealing material with a pressure sensitive adhesive to adhere the sealing material to the carrier tape such as to permit removal of the sealing material after adhesion to the carrier tape. Hansen et al. do teach the sealing material with a pressure sensitive adhesive to adhere the sealing material to the carrier tape such as to permit removal of the sealing material after adhesion to the carrier tape (col. 3, lines 58-68, col. 8, lines 24-56). The lower seal layer having a low melting point (polyethylene) and upper high melting point layer (polyester) joined to the seal layer is taught by Hansen et al. col. 8, lines 24-34. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided in the chemical storage apparatus of Guigan, the pressure sensitive adhesive as taught by Hansen et al. in order to prevent contamination of the device during storage and incubation (col. 2, lines 19-22).

Regarding the number of aliquots (wells) and the dimensions of the carrier tape roll, it would have been an obvious matter of design choice to include such dimensions and number of

wells in the carrier tape of Guigan, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guigan (USP 3,620,678) in view of Tidemann *et al* (USP 5,526,935).

Guigan does teach holes 5 perforating the carrier tape between the chemical receiving wells (column 4, lines 56-57, Fig. 1). Guigan does not teach the step of evacuating space between the seal material and the carrier tape at the time of sealing. Tidemann *et al* do teach the use of an aperture 118 to apply a vacuum to the well which evacuates the space between the seal material 120 and the carrier tape 102. (column 5, line 29-30, Fig. 2). Such a step of evacuation allows for more efficient loading of the wells with components (column 5, lines 29-30).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the method of Guigan with the step to evacuate the space between the seal material and the carrier tape, as taught by Tidemann *et al*, in order to allow for more efficient loading of the wells with components.

Response to Arguments

12. Applicant's arguments filed April 6, 2001 have been fully considered but they are not persuasive. Applicant argues in regard to claim 1, that Guigan (USP 3,620,678) does not teach wells which are thermally formed. Examiner points to the process of heat formation of the wells with a die taught by Guigan (column 9, lines 23-34). No manufacturing method for "thermally forming" or "thermoforming" the wells is disclosed in the specification or the claims, the claims are drawn to method of chemical compound storage not the formation of the wells. Additionally,

a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The wells of Guigan have clearly been "thermally" formed (column 4, lines 30-39).

Conclusion

13. No claims allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697.

The fax number for the organization where this application or proceeding is assigned is (703) 305-7718 for official papers prior to mailing of a Final Office Action. For official papers after mailing of a Final Office Action, use fax number (703) 305-3599. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex

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